

HFI-35 4/2/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service d1815b
Food and Drug Administration

Refer to: CFN 1122618

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

May 21, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Isaac B. Samuel, President
Elite Spice, Incorporated
7151 Montevideo Road
Jessup, Maryland 20794

Dear Mr. Samuel:

During an inspection of your firm's ethylene oxide (ETO) sterilization operation for spices, conducted by the Food and Drug Administration on April 23 and 27, 1998, our investigators documented violations of Section 402(a)(4) of the Food, Drug, and Cosmetic Act, and Title 21, Code of Federal Regulations (CFR), Part 110. Significant deviations include the following:

The effectiveness of the ETO treatment for controlling microorganisms in spices is not adequately verified, in that:

- 1) there is no documentation of the calibration and/or maintenance of the ETO scale, temperature probes, and timers used for the ETO cycles;
- 2) there is no emergency alarm or warning system to indicate failure during an ETO cycle (i.e., temperature, humidity, ETO concentration, and time); and
- 3) there is no documentation that the temperature time, humidity, or ETO concentration required for the cycle was maintained throughout the duration of the cycle.

The aforementioned violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

Mr. Isaac B. Samuel

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You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice. Such actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Wiley T. Williamson, III, Compliance Officer, Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201. Mr. Williamson can be reached at (410) 962-4366, Extension 136.

Sincerely,

A handwritten signature in cursive script, reading "Carl E. Draper", with a long horizontal flourish extending to the right.

CARL E. DRAPER
Acting District Director